

MIOSTAT™ Intraocular Solution for Injection

Carbachol 150 microgram/1.5 mL (0.01%)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you are given Miostat.

This leaflet answers some common questions about Miostat Solution for Injection. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from
www.ebs.tga.gov.au

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Miostat against the benefits they expect it will have for you.

The information in this leaflet applies to Miostat only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Miostat is used for

Miostat contains carbachol which belongs to a group of medicines called parasympathomimetics.

This medicine works by stimulating the muscles inside the eye that are responsible for the contraction of the pupils.

Your doctor will inject Miostat into your eye to constrict your pupils during surgery.

Ask your doctor if you have any questions about why this medicine is being used.

Use in children

The safety and effectiveness of Miostat Solution for Injection has not been established.

Before you are given Miostat

When you must not be given it

Miostat should not be given to you if you have an allergy to:

- Carbachol
- Any of the ingredients in Miostat which are listed at the end of this leaflet under "Product description".
- Natural latex.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing

- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin.

Do not use Miostat if:

- **the vial/packaging shows signs of tampering**
- **the expiry date on the injection vial/carton has passed.**

If this medicine is used after the expiry date has passed, it may not work.

If you are not sure whether Miostat should be used in your case, talk to your doctor.

This medicine has been developed for use in the eye only. It is not to be swallowed.

Before you are given it

Tell your doctor if:

- **you have allergies to any other medicines or any other substances such as foods, preservatives or dyes**
- **you have or have had any medical condition, especially the following:**
 - heart failure
 - asthma
 - stomach ulcer
 - stomach spasm
 - hyperthyroidism which is caused by an overactive thyroid gland
 - urinary tract obstruction
 - Parkinson's disease
- **you are pregnant or intend to become pregnant.**
Your doctor will discuss the

possible risks and benefits of using Miostat during pregnancy.

- **you are breastfeeding or intend to breastfeed.**

Your doctor will discuss the possible risks and benefits of using Miostat when breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you are given Miostat.

Ask your doctor for advice on the risks and benefits involved.

Taking or using other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy at a pharmacy, supermarket or health food shop without a doctor's prescription.

Your doctor will decide whether or not to give you Miostat.

How Miostat is given

How much is used

Miostat is given as an injection into the eye(s) by a doctor during surgery.

Your doctor will decide on the amount of Miostat to be put into your eye(s) during surgery.

After you are given Miostat

Things to be careful of

Be careful driving or operating machinery until you know how Miostat affects you and your vision.

As with any eye medicines, temporary blurred vision or other visual disturbances may affect the ability to drive or use machinery in some people. If blurred vision occurs, wait until your vision is

clear before driving or operating machinery.

If you are given too much (overdose)

The doctor giving you Miostat will be experienced in the use of this medicine, so it is unlikely that you will be given an overdose.

If you feel you have been given too much Miostat, immediately telephone the Poisons Information Centre (in Australia call 13 11 26; in New Zealand call 0800 POISON or 0800 764 766), your doctor, or go to Accident and Emergency at the nearest hospital.

Side Effects

Tell your doctor as soon as possible if you do not feel well after Miostat use.

All medicines can have side effects. Sometimes they are serious, however most of the time they are not. You may need to seek medical treatment if you get some of the side effects.

Do not feel alarmed by the following list of possible side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- Flushing
- Sweating
- Stomach cramps or pain
- Headache
- Blurred vision
- Gradual loss of vision
- Redness in the eye
- Clouding, blistering or swelling of the front of the eye
- Eye pain, sensitivity to light
- Sensation of fullness in the bladder.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following symptoms:

- Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body
- Retinal detachment has been reported when used in certain susceptible individuals. Symptoms include seeing bright flashes of light with floaters, progressing to a loss of sight.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any unwanted effects even if they do not appear in the list above.

Other side effects not listed above may also occur in some patients.

After using Miostat

Storage

MIOSTAT is usually stored in the doctor's surgery or hospital, or at the pharmacy.

However, if you need to store Miostat keep it in a cool, dry place where the temperature stays below 25° C. Do not freeze Miostat.

Do not leave Miostat in the car, in the bathroom or in other warm, damp places.

Heat and temperature can destroy some medicines.

Keep Miostat and all other medicine in a safe place.

Keep it where children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Product description

What it looks like

Miostat is a clear solution that comes in a 1.5 mL vial.

The vial stopper contains natural rubber (latex).

Ingredients

Miostat contains carbachol 150 micrograms in 1.5 mL (0.01%) as the active ingredient.

Miostat also contains:

- Sodium chloride
- Potassium chloride
- Calcium chloride dihydrate
- Magnesium chloride hexahydrate
- Sodium acetate
- Sodium citrate dihydrate
- Sodium hydroxide and/or hydrochloric acid (to adjust pH)
- Water for Injections.

Supplier

Miostat is supplied in Australia by:

Alcon Laboratories (Australia) Pty
Ltd

ABN 88 000 740 830

15 Talavera Road

Macquarie Park NSW 2113

Australian registration number

Aust R No: 40624.

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